UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

June



MEMORANDUM

6/15/2017

SUBJECT: Acute Toxicity Review for BARDAC 205M RTU, EPA Reg. No.: 6836-289

FROM: Narayanan Parthasarathy

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Product Science Branch

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TO: Jose Gayoso, PM Team 36 /Timothy Young

Regulatory Management Branch II Antimicrobials Division (7510P)

 Registrant: Lonza Inc

 Decision No.: 501668
 Submission No.: 999777
 E-Sub No.:

 DP No.: 438406
 Action Code: 676

 MRID No(s).: 45206503-45206508

Formulation from label Active Ingredient(s) CAS #(s) % weight PC code(s) 069165 32426-11-2 Octyl Decyl dimethyl ammonium chloride 0.0138% 069166 5583-94-3 Dioctyl Dimethyl Ammonium Chloride 0.0055% Didecyl dimethyl ammonium chloride 7173-51-5 0.0083% 069149 68424-85-1 Alkyl* dimethyl benzyl ammonium chloride 0.0184% 069105 *(50%C₁₄, 40%C₁₂, 10% C₁₆) Other Ingredients 99.9540%

100.0000%

Total

I. BACKGROUND

In response to the PDCI (069105-30933) the Registrant, Lonza Inc, has submitted acute toxicity data to support Reregistration for their product: *BARDAC 205M RTU*, EPA Reg. No. 6836-289. The registrant had provided 8-month response to the Product Data Call-in Notice. Case #0350 ADBAC- ID# PDCI-069105-30933 Alkyl dimethyl benzyl ammonium chloride Case #3003 DDAC - ID# PDCI-069149-30855 Didecyl dimethyl ammonium chloride Case #3003 DDAC - ID# PDCI-069165-30857 Octyl Decyl dimethyl ammonium chloride Case #3003 DDAC - ID# PDCI-069166-30858 Dioctyl Dimethyl Ammonium Chloride

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-35 – Data Matrix (10/26/2016)	⊠	
Cover letter (1/12/2016)	\boxtimes	
Transmittal document		
Basic CSF, (12/14/2016)	\boxtimes	
Proposed label,	\boxtimes	
Acute Oral Toxicity Study (OSCPP 870.1100)	\boxtimes	
Acute Dermal Toxicity Study (OSCPP 870.1200)	\boxtimes	
Acute Inhalation Toxicity Study (OSCPP 870.1300)	\boxtimes	
Primary Eye Irritation Study (OSCPP 870.2400)	\boxtimes	
Primary Skin Irritation Study (OSCPP 870.2500)	\boxtimes	
Dermal Sensitization Study (OSCPP 870.2600)	⊠	
Comments:		•

III. FINDINGS/RECOMMENDATIONS

The Chemistry and Toxicology Team (CTT) had reviewed *BARDAC 205M RTU*, EPA Reg. No 6836-289, on 12/12/2000 and assigned the following acute toxicity profile.

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	45206503	IV	Acceptable
Acute Dermal Toxicity	45206504	IV	Acceptable
Acute Inhalation Toxicity	45206505	IV	Acceptable
Primary Eye Irritation	45206506	IV	Acceptable
Primary Skin Irritation	45206507	IV	Acceptable
Dermal Sensitization	45206508	Nonsensitizer	Acceptable

CONCLUSION

- 1) The above Acute Toxicity Profile will be retained for *BARDAC 205M RTU*, EPA Reg. No 6836-289.
- 2) The registrant had provided satisfactory 8-month response to reregistration of the subject product.

V. PRODUCT LABELING

The proposed label with signal word and precautionary statements is acceptable.